

Reissue Application of
U.S. Patent No. 5,637,310
Atty. Docket No. 14509-C2 RI

it. On January 22, 2001, the U.S. Patent On January 22, 2001, the U.S. Patent & Trademark Office ("PTO") declared Interference No. 104,646 between the assignee of the '310 patent, SmithKline Beecham Corp. ("SKB"), and the party Rasmusson, whose assignee is Merck & Co., Inc. As declared, the interference involved a pending Rasmusson application and three SKB patents: U.S. Patent No. 5,300,294 (the '294 patent), U.S. Patent No. 5,496,556 (the '556 patent), and the '310 patent here sought to be reissued.*

Claims 1 and 2 of the '310 patent, read as follows:

1. A method of treating human prostatic adenocarcinoma which comprises administering to a subject in need thereof an oral dosage unit containing from about 1 mg. to about 500 mg. of a steroid 5- α -reductase inhibiting compound from 1-6 times during a twenty four hour period.
2. The method of claim 1 in which the steroid 5- α -reductase inhibiting compound is 17 β -(N-t-butylcarboxamide)-androst-3,5-diene-3-carboxylic acid.

The sole count of the interference specifies several alternative possibilities, including "The method of claim 1 of the '310 patent wherein the steroid 5- α -reductase inhibitor compound is 17 β -(N-t-butylcarboxamide)-5- α -androst-1-ene-4-aza-3-one." By the amendment herein, claim 3 is added to the '310 patent to more narrowly and specifically claim the subject matter of the count of the interference. Thus, proposed claim 3 differs from existing claim 1

* Recently, the '294 patent was dropped from the interference because it had expired for failure to pay the maintenance fee on time. A petition to accept a late payment of the maintenance fee is pending, and if the petition is granted, the '294 patent will again be in interference with the Rasmusson application. In the meantime, the interference is in the preliminary motions period, proceeding on the '556 and '310 patents.

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only by the substitution of the specific compound prescribed in the interference count, 17 β -(N-t-butylcarboxamide)-5- α -androst-1-ene-4-aza-3-one, also known as "finasteride," for the recitation in claim 1 of the '310 patent of "a steroid 5- α -reductase inhibiting compound." Thus, claims 1-3 are pending in this reissue application.

There is no new matter involved in this addition of claim 3. The compound finasteride is described in chemical nomenclature exactly as claimed, *i.e.*, as 17 β -(N-t-butylcarboxamide)-5- α -androst-1-ene-4-aza-3-one, in the specification at col. 2, lines 66-67 of the '310 patent. Moreover, it is expressly described as a steroid 5- α -reductase inhibitor in col. 2, lines 64-65, of the '310 patent.

Application No. 08/452,765 ("the '765 application") filed May 30, 1995, which led to the '310 patent was a continuation of Application No. 08/170,481 ("the '481 application") filed December 20, 1993, which issued as the '556 patent, and which in turn was a continuation of Application No. 07/544,709 ("the '709 application") filed June 27, 1990, which issued as the '294 patent. The same disclosure of finasteride and that it is a steroid 5- α -reductase inhibitor as is in the '765 application and '310 patent appears in the earlier '481 and '709 applications. *See* the '556 patent, col. 2, line 66-col. 3, line 2, and the '294 patent, col. 3, lines 3-6. Patent Owner thus claims the benefit of the December 20, 1993, filing date of the '481 application, and the June 27, 1990, filing date of the '709 application for proposed claim 3.

Moreover, claim 3 is narrower than claim 1 in the use of the specific compound

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finasteride as the steroid 5- α -reductase inhibitor of claim 1, and is otherwise identical to claim 1. The addition of claim 3, therefore, does not make the '310 reissue application a *broadening* reissue under 35 U.S.C. § 251. As explained in the Manual of Patent Examining Procedure, August 2001 ("MPEP"), "A broadened reissue claim is a claim which enlarges the scope of the claims of the patent, *i.e.*, a claim which is greater in scope than each and every claim of the original patent." MPEP § 1412.03, at page 1400-16. Claim 3 does not enlarge the scope of the claim of the '310 patent.

Nor is there any impermissible "recapture." The omission or broadening of a limitation in the patent claim is required for there to be recapture, and "the limitation now being omitted or broadened in the present reissue [...has to have been] originally presented/argued/stated in the original application to make the claims allowable over a rejection or objection made in the original application." MPEP § 1412.02, at page 1400-13. Neither of these conditions apply to added claim 3.

Finally, this preliminary amendment to add claim 3 is in accord with the interference rules. Under the provisions of 37 C.F.R. § 1.633(i), when an opponent in an interference moves for judgment of unpatentability of a party's patent, the party can respond by filing a motion to add a claim to the interference under § 1.633(c)(2). In the interference, on September 28, 2001, the party Rasmusson filed a Preliminary Motion 1 under 37 C.F.R. § 1.633(a), for judgment of unpatentability of '310 patent claim 1 over prior art. The motion, in part, alleges that claim 1 of the '310 patent is too broad in the sense that if interpreted to encompass the use of certain

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compounds disclosed in the prior art, it would be invalid. But that attack by Rasmusson would not be applicable to a claim that is specific to the use of finasteride. The present amendment to add claim 3 to the '310 reissue application is thus a proper response to Rasmusson's motion.

For the foregoing reasons, Patent Owner respectfully submits that claim 3 is proper and its allowance in this reissue application is requested.

If there are any fees due in connection with the filing of this Preliminary Amendment not already accounted for, please charge the fees to Patent Owner's Deposit Account No. 19-2570.

Respectfully Submitted,

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Date

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